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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pasika	7414.0025	8658

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,910

Applicant(s)

PASIKA ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/21/03 (RCE 11/23/03).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 21 August 2003 has been entered.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 34-45. Claims 1, 2, 4, 5, 7-13, 16-24, 26, 27, 29-33 remain withdrawn. Claims 3, 6, 14, 15, 25, and 28 have been cancelled.

INFORMATION DISCLOSURE STATEMENT

Several references in the 'Information Disclosure Statement', filed 24 March 2003, are lined through. Said references appear to be in duplicate to those that have been previously cited and considered (Refer to 'Information Disclosure Statement', filed 01 August 2001; and PTO-892, mailed 15 May 2002).

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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SCOPE OF ENABLEMENT

Claims 34-45 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call” via the disclosed Envelope Caller (as outlined below), does not reasonably provide enablement for the analysis of the signal “to determine if the a signal meets a threshold test of an allele caller making a correct call” by all other means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Applicants' argue new claims 34-45 are enabled for the full breadth of the claims, wherein the new claims are directed to a computer-implemented method, a system, and a computer-readable medium for processing a signal. This is not agreed with.

The instant claims broadly embrace other means for "analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call" and therefore the claims are not commensurate in scope with the disclosure. The threshold determination (i.e. test) is disclosed as being performed by the Envelope Caller, wherein the specification states:

"Using the three largest energy levels (E1, E2, and E3, respectively – which in the figure corresponds to panels 1, 2, and 5), the Envelope Caller algorithm performs a "threshold determination (step 314)." (page 15, lines 1-3 of the Specification)

No other procedures are disclosed for threshold determination. The specification discloses only procedures for threshold determination by an Envelope Caller process wherein the outlined procedures are: 1) Calculate the derivative of the original signal thereby determining the minima and maxima of the original signal; 2) Discard the minima of the original signal; 3) Connect the maxima points of the original signal to obtain an "envelope of the signal"; 4) Calculate the derivative of the "envelope of the signal" to determine the minima and maxima of the "envelope of the signal"; 5) Discard the minima of the "envelope of the signal"; 6) Connect the maxima points of the "envelope of the signal" to obtain a "third signal"; 7) Divide the "third signal" into panels (wherein a panel is defined as one where the signal is initially low, then increases rapidly, and falls off again towards the baseline termination of the minima and maxima); 8) If at least three panels exist calculate the energy level for each panel by summing the square of each element in the panel; 9) Consider only the three regions with the greatest energy; 10) Choose the two dominant peaks in the signal; 11) Make an allele call on the maxima in the two panels with

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the greatest energy (pages 15-17 of the Specification, Figure 3A, and Figure 7). None of these above outlined steps or elements are limitations of the instant claims. The specification does not provide guidance, direction, or examples as to other types of signal analysis to determine if a signal meets a threshold thereby making an allele call. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37, 39-41, and 43-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 35, 39, 43, and all claims dependent therefrom recite the limitation “wherein the nucleic acid information is used to determine nucleic acid length, panel determination, and energy computation” which is confusing. It is unclear if the nucleic acid length, panel determination, and energy computation information determined from the nucleic acid information is intended to be part of the “analyzing the signal...” step. For example, is the determined nucleic acid length, panel determination, and energy computation information of claim 35 intended to be information for the “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call” step of claim 34? If this is Applicants

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intent, the claims (as written) do not appear to represent this. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 38, and 42 are rejected under 35 U.S.C. § 102(b) as being anticipated by Palsson et al. (Using Quality Measure to Facilitate Allele Calling in High-Throughput Genotyping. Genome Research. Volume 9, pages 1002-1012).

Palsson et al. describes a computer-implemented method of combining an allele-calling program with quality measures and empirically derived criteria (i.e. peak height and shift) to efficiently and accurately call alleles (Abstract). The computer program (Decode-GT) receives results (i.e. electropherogram(s); signal representing nucleic acid information) from an allele-calling program (TrueAllele) and categorizes the data as good allele calls or bad allele calls based upon a threshold that is established by quality measures, peak heights, and peak shifts (page 1003, right column, lines 45-55; Figures 6, 7, and 8). Allele calls are made for the signal if the threshold is met (represented as the accepted good calls), whereas allele calls that do not meet the threshold (categorized as bad calls) are discarded (page 1003, beginning on the right column line 40 to page 1004, right column, line 4; and page 1010, right column, lines 11-18). The authors indicate the utilization of PC workstation (i.e. containing processor, memory, computer readable medium) for the described computer-implemented method and that a copy of

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the computer program is available (page 1003, right column, lines 16-19; and page 1011, right column, lines 19-21). Thus, Palsson et al. anticipates the instantly claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *March 5, 2004*Examiner Initials: *CSM*

MPW
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

7 March 2004